FORM APPROVED: OMB No. 0910-0052. Expiration Date: April 30, 2000. *See Instructions for OMB Statement.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. **REGISTRATION NUMBER**

2. **DISTRICT CODE** (FDA Use Only)

3. **REASON FOR SUBMISSION**
.1 ☐ ANNUAL REGISTRATION
.2 ☐ INITIAL REGISTRATION
.3 ☐ CHANGE IN INFORMATION

FOR FDA USE ONLY

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in items 4 - 6, and any changes in your mailing address in items 8 - 10. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 12.2 and the phone number of your actual location in item 6.6. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p) and can result in a fine of up to $1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 33.3(a)).

LEGAL NAME AND LOCATION PHONE

ENTER CORRECTIONS
4. LEGAL NAME
5. STREET ADDRESS

6.1 CITY 6.2 STATE 6.3 ZIP CODE -
6.4 COUNTRY
6.5 P.O. BOX 6.6 PHONE ( )

7. **OTHER NAMES USED AT THIS LOCATION** (Include trade name, doing-business as, previous names, and other firms co-located. If applicable, include registration number.)

MAILING ADDRESS OF REPORTING OFFICIAL

ENTER CORRECTIONS
8. NAME OF FACILITY
9. STREET ADDRESS

10.1 CITY 10.2 STATE 10.3 ZIP CODE -

11. **TYPE OF OWNERSHIP**
.1 ☐ SINGLE PROPRIETORSHIP
.2 ☐ PARTNERSHIP
.3 ☐ CORPORATION profit___ non-profit___
.4 ☐ COOPERATIVE ASSOCIATION
.5 ☐ FEDERAL *(non-military)*
.6 ☐ U.S. MILITARY
.7 ☐ STATE
.8 ☐ COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
.9 ☐ OTHER *(Specify):* _____

12. **REPORTING OFFICIAL'S SIGNATURE**

12.1 TYPED NAME
12.2 PHONE 12.3 DATE

13. **TYPE ESTABLISHMENT** *(Check all boxes which describe routine or autologous operations.)*
.1 ☐ COMMUNITY (NON-HOSPITAL) BLOOD BANK
.2 ☐ HOSPITAL BLOOD BANK
.3 ☐ PLASMAPHERESIS CENTER
.4 ☐ PRODUCT TESTING LABORATORY
a. ___ INDEPENDENT
___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
.5 ☐ HOSPITAL TRANSFUSION SERVICE
a. ___ APPROVED FOR MEDICARE REIMBURSEMENT
___ NOT APPROVED FOR MEDICARE REIMBURSEMENT

14a. U.S. LICENSE NO. -

AUXILIARY FACILITIES
.6 ☐ COMPONENT PREPARATION FACILITY
.7 ☐ COLLECTION FACILITY
.8 ☐ DISTRIBUTION CENTER

14b. U.S. LICENSE NO. OF PARENT FIRM -

.9 ☐ OTHER *(Specify):* _____

15. **PRODUCTS**

PRODUCTS		COLLECT ALLOGENEIC (.1)	COLLECT AUTOLOGOUS (.2)	COLLECT DIRECTED (.3)	MANUAL PHERESIS (.4)	AUTOMATED PHERESIS (.5)	IRRADIATED BLOOD PRODUCTS (.6)	PREPARE (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)
WHOLE BLOOD	1				■	■		■		
WHOLE BLOOD CRYOPRECIPITATE REMOVED	2	■	■	■	■	■				
WHOLE BLOOD LEUKOCYTES REDUCED	3	■	■	■	■	■				
RED BLOOD CELLS	4	■	■	■	■					
RED BLOOD CELLS LEUKOCYTES REDUCED	5	■	■	■	■	■				
RED BLOOD CELLS FROZEN	6	■	■	■	■	■				
RED BLOOD CELLS DEGLYCEROLIZED	7	■	■	■	■	■				
RED BLOOD CELLS REJUVENATED	8	■	■	■	■	■				
RED BLOOD CELLS REJUVENATED FROZEN	9	■	■	■	■	■				
RED BLOOD CELLS REJUVENATED DEGLYCEROLIZED	10	■	■	■	■	■				
CRYOPRECIPITATED AHF	11	■	■	■	■	■				
PLATELETS	12	■	■	■						
LEUKOCYTES / GRANULOCYTES	13	■	■	■						
PLASMA	14	■	■	■						
PLATELET RICH PLASMA	15	■	■	■						
FRESH FROZEN PLASMA	16	■	■	■						
LIQUID PLASMA	17	■	■	■						
THERAPEUTIC EXCHANGE PLASMA	18	■	■	■			■	■		
SOURCE LEUKOCYTES	19	■	■	■			■	■		
SOURCE PLASMA	20	■	■	■			■	■		
RECOVERED PLASMA	21	■			■	■	■			
BLOOD PRODUCTS FOR DIAGNOSTIC USE	22		■	■	■	■	■			
BLOOD BANK REAGENTS	23	■	■	■	■	■	■			
OTHER	24									

16. a. HIV PROFICIENCY TEST PROGRAM NAME:
b. HBsAg PROFICIENCY TEST PROGRAM NAME:

Created by Electronic Document Services/USDHHS: (301) 443-2454 EF

INSTRUCTIONS FOR COMPLETING BLOOD REGISTRATION FORM 2830

Completion of FDA 2830 is required under Part 607, Title 21, CFR, for all blood establishments collecting, manufacturing, preparing, storing under controlled conditions for further distribution, or processing blood and blood products. The Food and Drug Administration (FDA) no longer requires Hospital Transfusion Services certified under the Medicare program to register. However, an establishment which collects autologous or directed units is considered to be a Hospital Blood Bank and is required to register.

Please review all computer entered data for accuracy and completeness.

Using RED ink, circle each incorrect item and PRINT all corrections and additions.

Note the following:

YOU MUST NOTIFY FDA WITHIN 5 DAYS IF YOU CHANGE LOCATION.

Items 4 through 6. ACTUAL LOCATION--These refer to the legal name (not the "doing-business-as" or other names in Item 7 and the address of the blood collection or preparation facility. **Include the 4 digit zip code extension. NOTE:** If blood collection and laboratory facilities are separated, but register as one location because of their close proximity, use the laboratory address.

Item 7. OTHER NAMES USED AT THIS LOCATION--Provide any other name by which your facility is commonly known, including any name not shown in Items 4 or 8, which is or was used at this location, including trade names, doing-business-as names, previous names and names of unaffiliated corporations at the same location, and include the registration number (in parentheses).

Items 8 through 10. MAILING ADDRESS OF REPORTING OFFICIAL--Provide the address to which official correspondence or inquiries should be directed if other than the actual address of the facility. The reporting official is the person appointed by the owner or operator to register the firm and answer all correspondence and inquiries relative thereto. **Include the 4 digit zip code extension.**

Item 11. TYPE OF OWNERSHIP--For Item 11.3, also check either "profit" or "non-profit."

Item 12. REPORTING OFFICIAL'S SIGNATURE--This "reporting official" is the person appointed by the owner or operator to register the firm and answer all the correspondence and inquiries relative thereto. Be sure to include the reporting official's phone number in Item 12.2. The validated registration form will be sent to the location shown for the registering establishment, and a copy will be sent to the reporting official if at another address.

Item 13. TYPE ESTABLISHMENT--(check all applicable boxes which describe your routine or autologous operations). If you check Hospital Transfusion Service (13.5) do not check any other block. Also, please *do not* check blocks 13.6 through 13.8 unless you operate as an auxiliary facility (e.g., donor center) for a U.S. licensed establishment.

.1 **Community Blood Bank (Non-hospital)**--A commercial or non-profit blood collection/processing facility, not located in a hospital, which may perform product testing and routinely distributes blood and/or blood products to one or more hospitals. An independent blood bank located inside a hospital but separately operated and owned is considered to be a Hospital Blood Bank (Item 13.2).

.2 **Hospital Blood Bank**--A hospital (or facility located within a hospital) which routinely performs pheresis, collects or processes Whole Blood into components, including the freezing, deglycerolizing, washing, irradiating, rejuvenating of, or reducing the number of leukocytes from Red Blood Cells. A hospital which performs autologous or directed collections is included in this category. A facility in this category usually performs product testing (such as blood grouping and hepatitis testing), as well as compatibility testing. A hospital which solely prepares Red Blood Cells or Recovered Plasma, however, is considered to be a Hospital Transfusion Service (Item 13.5). A hospital which collects Source Plasma under licensure should also check "Plasmapheresis Center."

.3 **Plasmapheresis Center**--An establishment licensed by the Center for Biologics Evaluation and Research which collects Source Plasma or Therapeutic Exchange Plasma for commercial distribution. If this location also collects Whole Blood for a licensed facility, "Collection Facility" should also be checked and the license number of the location (e.g. 0190-023) for which collection is performed should be noted in block 14.b. Hospitals which perform plasmapheresis for research purposes only or to prepare transfusion products such as Plasma or Platelets should **NOT** check this box.

.4 **Product Testing Laboratory**--A separate facility that performs routine blood and plasma donor testing. Item 13.4a concerning type establishment **MUST** also be answered.

.5 **Hospital Transfusion Service**--A hospital that performs compatibility tests (crossmatching) for blood or blood components but does NOT routinely collect allogeneic or autologous blood, or process Whole Blood into components (except Red Blood Cells or Recovered Plasma). Hospitals which freeze, deglycerolize, wash, irradiate, rejuvenate or reduce the number of leukocytes from Red Blood Cells are considered to be a Hospital Blood Bank (Item 13.2). Item 13.5a concerning Medicare program reimbursement MUST be answered.

.6 **Component Preparation Facility**--An intermediate processing facility which prepares components from blood collected by a mobile or fixed collection site but does not perform product testing. If applicable, indicate the complete license number and location under which the collection facility operates (e.g. 0190-023) in Item 14.b. If you also collect, or redistribute, Item 13.7 or 13.8 should also be checked.

.7 **Collection Facility**--A facility which performs blood collections or pheresis but does not test. If applicable, indicate the complete license number and location under which the collection facility operates (e.g. 0190-023) in Item 14.b. If you also redistribute the final product after it has been processed and returned to you by the blood bank, Distribution Center, Item 13.8, should also be checked.

.8 **Distribution Center**--A facility which stores blood or a blood product under specific controlled conditions prior to shipping it to the final user, including suppliers of source material for further manufacture such as Recovered Plasma, Source Plasma, and Whole Blood, Red Blood Cells, or Platelets for diagnostic product use. For example, Whole Blood facilities which intend to redistribute the product to transfusion centers, Source Plasma warehouses which intend to redistribute the product to fractionators or Recovered Plasma holding facilities or brokers intending to redistribute the product to diagnostic product manufacturers or fractionators. A transfusion service is not considered to be a "distribution center" since it holds the product over a relatively short period of time and does not intend to redistribute. If applicable, indicate the complete license number and location under which the distribution center operates (e.g. 0190-023) in Item 14b.

.9 **Other (specify)**--This includes firms which manufacture fractionated blood derivatives, diagnostics and other blood products, or independent facilities which irradiate blood products.

Item 14. LICENSE--U.S. Licenses are issued under Section 351 of the Public Health Service Act by the Center for Biologics Evaluation and Research to firms which apply for licensure and otherwise qualify. Licenses are only appropriate for firms engaged in *interstate* commerce. License number, for the purposes of registration, should include the location number suffix assigned to the actual location (e.g. 0190-023). Only "Community Blood Banks," "Hospital Blood Banks," "Plasmapheresis Centers," "Product Testing Laboratories," if applicable, and "Others" are assigned unique license numbers. Other auxiliary facilities such as "Component Preparation Facility," "Collection Facility," and "Distribution Center," operate under the license of a parent establishment and should so indicate in Item 14b. The license number should not be entered in both 14a. and 14b.

Item 15. PRODUCTS--All products routinely collected for allogeneic, autologous or directed use, or products prepared, tested or stored for distribution to other firms should be checked. Products obtained as a by-product of a therapeutic procedure and immediately disposed of are not to be included. Similarly, products prepared under emergency conditions are also excluded. The Agency defines an emergency as a situation which demands immediate action which has been suitably documented in writing by a responsible person. **Do not fill in shaded areas.**

(.1) **Allogeneic Collection**--refers to blood collected for transfusion to other than the donor or a known recipient.

(.2) **Autologous Collection**--refers to blood collected for transfusion (at a later time) to the donor.

(.3) **Directed Collection**--refers to blood collected for transfusion to a known recipient.

(.4) **Manual Pheresis**--refers to functions such as plasmapheresis, platelet pheresis and leukapheresis. Plasma obtained from a therapeutic plasma exchange, but autoclaved and destroyed would not be checked. If, however, that plasma is routinely shipped as a product, then Item 15.18(.4) or (.5) would be checked, depending on pheresis method.

(.5) **Automated Pheresis**--refers to the collection by automated equipment of Red Blood Cells, Platelets, Leukocytes / Granulocytes or Plasma.

(.6) **Irradiated Blood Products**--refers to blood products which have been irradiated before transfusion.

(.7) **Prepare**--refers to functions such as component preparation wherein the product is prepared from Whole Blood. For example, if you prepared Platelets from Whole Blood, check 15.12(.7); whereas if you obtain Platelets by automated pheresis, check 15.12(.5). Platelets obtained by manual pheresis should be indicated by checking 15.12(.4).

(.8) **Test**--refers to product testing such as blood grouping, syphilis, hepatitis, anti-HIV protein electrophoresis testing as well as compatibility testing (crossmatching). It does not include daily quality control tests of reagents.

(.9) **Store and Distribute to Others**--refers to the storage of a product under controlled conditions for distribution to other firms.

INSTRUCTIONS FOR COMPLETING BLOOD REGISTRATION FORM 2830 (Continued)

Item 16a. HIV PROFICIENCY TEST PROGRAM--Indicate the name of your HIV proficiency test program. If none, write "None."

b. HBsAg PROFICIENCY TEST PROGRAM--Indicate the name of your HBsAg proficiency test program. If none, write "None."

Any product not specified in Items 15.1 through 15.23 must be listed in 15.24 "Others." A completed FDA 2657, "Drug Product Listing," or FDA 2892, "Medical Device Listing," must be submitted for any product not previously listed with the Agency in order that an NDC Labeler Code may be assigned. Do not list products held for final use such as albumin, reagents, immune globulins, etc.

BE SURE THE REPORTING OFFICIAL HAS SIGNED AND DATED THIS FORM. This is the person designated by your firm as authorized to register the firm officially. The telephone number of the reporting official should be indicated in Item 12.2.

After completion, return the form to:

Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-375)
1401 Rockville Pike, Rockville, MD 20852-1488
ATTENTION: Blood Registration Coordinator
Phone No. (301)-827-3546

PRODUCT DEFINITION

.1 **Whole Blood**--All blood collected from human donors for transfusion to human recipients using an approved anticoagulant preservative solution.

.2 **Whole Blood Cryoprecipitate Removed**--Whole Blood from which the plasma is processed to separate cryoprecipitate. The supernatant plasma is then recombined with the red cell component. This is also called Modified Whole Blood, Reconstituted Whole Blood, or Cryo-Poor Whole Blood.

.3 **Whole Blood Leukocytes Reduced**--Whole Blood from which the plasma is processed to separate leukocytes and then recombined with the Red Blood Cell component.

.4 **Red Blood Cells**--Red Blood Cells remaining after separating plasma from human blood.

.5 **Red Blood Cells Leukocytes Reduced**--Red Blood Cells which have been washed or processed by centrifugation or filtration (other than during transfusion) to reduce the number of leukocytes.

.6 **Red Blood Cells Frozen**--Red Blood Cells separated from the plasma and stored at ultra-low temperature in the presence of a cryoprotective agent and which may be preserved for long periods of time.

.7 **Red Blood Cells Deglycerolized**--Red Blood Cells which have been washed free of the glycerol in which they have been stored.

.8 **Red Blood Cells Rejuvenated**--Red Blood Cells which have been treated with a rejuvenating solution such as pyruvate inosine to restore cell integrity.

.9 **Red Blood Cells Rejuvenated Frozen**--Red Blood Cells which have been treated with a rejuvenating solution and then frozen and stored at ultra-low temperatures in the presence of a cryoprotective agent.

.10 **Red Blood Cells Rejuvenated Deglycerolized**--Red Blood Cells which have been treated with a rejuvenating solution, frozen using a cryoprotective agent, and then washed free of the rejuvenating solution and glycerol.

.11 **Cryoprecipitated AHF**--A preparation containing antihemophilic factor obtained from a single unit of plasma.

.12 **Platelets**--Platelets collected from a single donor and resuspended in a specified volume of original plasma.

.13 **Leukocytes / Granulocytes**--White Blood Cells (leukocytes) collected from a single donor and suspended in a specific volume of original plasma intended for patient infusion.

.14 **Plasma**--The fluid portion of one unit of human blood intended for intravenous use which, in a closed system, has been collected, stabilized against clotting, and separated from cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at -18˚C or colder.

.15 **Platelet Rich Plasma**--Single donor plasma which contains at least 250,000 Platelets per microliter and is stored at 1 - 6˚C or 20 - 24˚C.

.16 **Fresh Frozen Plasma**--Single donor plasma prepared within 8 hours of collection and stored at -18˚C or colder.

.17 **Liquid Plasma**--Single donor plasma which has been separated from the red cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at 1 - 6˚C.

.18 **Therapeutic Exchange Plasma**--Plasma obtained from a patient who undergoes plasma exchange (also referred to as therapeutic plasmapheresis). The name of the broker or manufacturer and the broker's location (city and state) should be indicated on this line or immediately below line .24.

.19 **Source Leukocytes**--White Blood Cells intended as source material for further manufacturing use.

.20 **Source Plasma**--The fluid portion of human blood collected by plasmapheresis (except plasma derived by therapeutic plasma exchange) and intended as a source material for further manufacturing use, includes source material intended for injectable and non-injectable products.

.21 **Recovered Plasma**--Plasma derived from single units of Whole Blood, or Plasma, or as a by-product in the preparation of blood components from Whole Blood collection for use in the manufacturing of licensed and/or unlicensed products. The names of the broker or manufacturer and the broker's location (city and state) should be indicated on this line or immediately below line .24.

.22 **Blood Products for Diagnostic Use**--Whole Blood, Red Blood Cells, or Platelets shipped for further manufacture into non-injectable products.

.23 **Blood Bank Reagents**--Diagnostic substances manufactured for commercial distribution used to characterize and determine the acceptability of blood or products for transfusion purposes. These include reagent Red Blood Cells, blood grouping reagents, antibody to HBsAg, etc. A separate FDA 2892, "Medical Device Listing," should be submitted for each product when a product is initially listed.

.24 **Other**--Other Products not denoted above, manufactured for commercial distribution, including fractionated blood derivatives such as immune globulins, albumin, etc. List each product individually on the FDA 2657, "Drug Product Listing," when submitting an initial product listing.

Paperwork Reduction Act Statement